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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,928	04/26/2001	Philippa Marrack	2879-76	2069
22442	7590	12/19/2003	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,928

Applicant(s)

MARRACK ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's Election, filed 8/01/03 is acknowledged.
2. Applicant's election of Group II, Claims 1-3, 9, and 14-17, with traverse, is acknowledged. In view of Applicant's arguments the restriction is hereby vacated. A new restriction follows. The Examiner apologizes for any inconvenience or delay.
3. Claim 1 links inventions I-XX. The restriction requirement among the linked inventions is subject to the nonallowance of linking claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.
4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1, 2, 4, 5, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to an IL-15 receptor, including an antibody, and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 424, subclass 278.1 and Class 530, subclass 388.22.
  - II. Claims 1-3, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising IL-15 or an IL-15 homologue, and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 424, subclass 351 and Class 530, subclasses 351 and 388.22.
  - III. Claims 1, 6, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to IL-15 and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 424, subclass 278.1 and Class 530, subclass 388.22 and 388.23.

IV. Claims 1, 7, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising a nucleic acid encoding IL-15 or an IL-15 homologue, and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 435, subclass 91.1 and Class 530, subclass 388.22.

V. Claims 1, 8, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to a regulatory region of a gene encoding IL-15 and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 435, subclass 91.1 and Class 530, subclass 388.23.

IV. Claims 1, 2, 4, 5, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to an IL-15 receptor, including an antibody, and an agent that binds to and degrades IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclass 388.22.

VII. Claims 1-3, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising IL-15 or an IL-15 homologue, and an agent that binds to and degrades IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclasses 351.

VIII. Claims 1, 6, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to IL-15 and an agent that binds to and degrades IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclass 388.23.

IX. Claims 1, 7, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising a nucleic acid encoding IL-15 or an IL-15 homologue, and an agent that binds to and degrades IL-2, classified in Class 435, subclass 91.1.

X. Claims 1, 8, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to a regulatory region of a gene encoding IL-15 and an agent that binds to and degrades IL-2, classified in Class 435, subclass 91.1 and Class 436, subclass 24.5.

XI. Claims 1, 2, 4, 5, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to an IL-15 receptor, including an antibody, and an agent

that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclass 388.22.

XII. Claims 1-3, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising IL-15 or an IL-15 homologue, and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclasses 351.

XIII. Claims 1, 6, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to IL-15 and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclass 388.23.

XIV. Claims 1, 7, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising a nucleic acid encoding IL-15 or an IL-15 homologue, and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 435, subclass 91.1.

XV. Claims 1, 8, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to a regulatory region of a gene encoding IL-15 and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XVI. Claims 1, 2, 4, 5, 13, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to an IL-15 receptor, including an antibody, and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XVII. Claims 1-3, 13, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising IL-15 or an IL-15 homologue, and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XVIII. Claims 1, 6, 13, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to IL-15 and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XIX. Claims 1, 7, 13, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising a nucleic acid encoding IL-15 or an IL-15 homologue, and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclasses 23.5 and 24.5.

XX. Claims 1, 8, 13, and 14-17,, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to a regulatory region of a gene encoding IL-15 and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XXI. Claims 18-33, drawn to a method to increase T lymphocyte memory, classified in Class 424, subclasses 184.1 and 278.1.

XXII. Claims 34-50, drawn to a method to reduce an autoimmune response, classified in Class 424, subclasses 184.1 and 278.1.

XXIII. Claim 51, drawn to a composition for decreasing an undesirable T cell response, classified in Class 424, subclasses 184.1 and 278.1.

5. Inventions I-XX and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in *in vitro* assays.

6. Inventions I-XX are different products. They are distinct because their structures and/or modes of action are different. Whereas the products of Groups I, VI, XI, and XVI comprise binding agents, generally proteins such as antibodies, the products of Groups IV, IX, XIV, and XIX comprise nucleic acids encoding proteins. Nucleic acids and proteins are physically and functionally distinct chemical entities, as are polypeptides and the binding proteins which bind them. Note that Groups XVI-XX comprise antisense DNA which comprise yet another patentably distinct invention. Thus, each of the combinations of inventions set forth in Groups I-XX above comprises a patentably distinct

invention.

7. Inventions XXIII and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in *in vitro* assays.

8. Inventions XXI and XXII are unrelated methods. Whereas the method of Group XXI would increase an immune response, the method of Group XII would reduce said response.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

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**Please Note:** inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600

  
12/13/03  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**